

REMARKS/ARGUMENTS

Currently in the case, after amendment, claims 1 - 5, 8, 9, 11-13, and 16-8 are rejected while claims 6,7,10,12,14,15&19 are objected to.

This Amendment responds to the aforementioned Office Action, wherein the claims as originally presented were rejected under Title 35 of United States Code, §§112, & 103. The Examiner's remarks have been carefully considered and, in view of the cited art, the claims which have amended to more particularly point out the distinctly claimed what Applicants regard as the subject matter of this present invention, it is sincerely believed that the claims which remain in the instant case patentably distinguish over all the prior art references. It is respectfully requested that this Application be re-examined in view of the following remarks, that the rejections be withdrawn, and that allowable subject matter be identified.

The points raised by the Examiner in the written office action will be responded to in the order they were discussed by the Examiner in the Office Action.

In paragraphs 1 & 2, the "Claim Objections" and "Drawings Objections" have been cured by claim amendment and proposed drawing amendment, respectively.

In paragraphs 3 and 4, a substantive rejection was made under 35 USC §103 as obvious over U.S Patent No 5,409,112 to

Sagstetter in view of U.S. Patent No. 3,746,155 to Seeley.

U.S. Patent No. 3,746,155 to Seeley, entitled TWO CAVITY SYRINGE PACKAGE, discloses a device for holding a syringe 10 and vial 11 where such items might be produced with extreme urgency by a doctor. The packaging is to insure a usable condition when opened and to give easy access especially for cardiac arrest (mid column 1). It is clear that this structure is a custom made structure in which known size medicine and syringe are closely fit.

U.S. Patent No 5,409,112 to Sagstetter, entitled "NEEDLE DISPOSAL SYSTEM COMPRISED OF BLOOD COLLECTION HOLDER AND COMPANION BIOHAZARD RECEPTACLE" discloses a container having a pair of one way disposal needle removal devices, 35, 50. The object of the invention is to provide irreversible positive locking means which won't "let go" of a needle being disengaged and insures that it cannot be withdrawn from the receptacle (column 2). It appears as if the container is not subdivided and that the two one-way engagement structures, like the gravity-drop opening adjacent the engagement structures, all lead into a central container.

(1) It makes no sense to combine the teachings of a disposal unit (Sagstetter) with a quick-access, new use emergency syringe and vial packaging (Seeley).

(2) In terms of needle disposal, Sagstetter can provide no

structure beyond Sagstetter as the structure of Seeley is for (a) quick access to a needle and vial set (sterile) and (b) is designed to be used oppositely from a disposal structure.

A key component of applicant's invention is the ability to use the structure for either (1) temporary storage of a used or new needle, or (2) permanent disposal of needles which have been used, as well as (3) isolation of each needle.

The Examiner states that Sagstetter has a needle holder with body, lid, main opening lockably coverable with a plurality of needle retaining openings in communication with said main opening, support structure of enabling support and a plurality of needle retaining openings in communication with said main opening for frictionally engaging and retaining said hypodermic needle by at least frictional engagement upon insertion of said hypodermic needle within said needle retaining opening, as well as enabling the hypodermic needle holder to be supported. Seeley is said to disclose a holder having a plurality of needle retaining openings associated with and in communication with isolated chambers.

Applicant takes exception to this characterization of both Sagstetter and Seeley.

- (1) Sagstetter is for DISPOSAL ONLY of needles.
- (2) Sagstetter does not retain each needle. The claim language "each needle retaining opening in communication with said

main opening for frictionally engaging and retaining said hypodermic needle". Sagstetter has two needle engagement openings, but no needle retaining openings. The needles of Sagstetter are disposed of the main central cavity. If each of the structures 35, 50 of Sagstetter were to RETAIN their needles, further needles could not be disposed of as the engagement/removal structures 35, 50 would be blocked.

- (3) In applicant's structure the needles are retained until a decision is made to dispose of them in which case the main cover is closed and the complete unit structure is disposed of.
- (4) Sagstetter cannot be said to have "each needle retaining opening associated with and in communication with an isolated chamber", but Seeley DOES NOT have needle retaining opening. A pre-formed space for holding a complete syringe with cover and a vial is NOT a NEEDLE RETAINING OPENING.
- (5) Applicant's claims require "each needle retaining opening in communication with said main opening". In Sagstetter, a flat piece of plastic covers both needle engagement openings separately. The slight reduction in surface to accommodate the door 3 does not form a main opening, but merely a means to make the cover flush when it is covering the needle engagement openings individually.
- (6) To the extent used, (a) Seeley is at WAR with the teaching

of both Sagstetter and the intent of the invention, and (b) for the purposes for which Seeley was used, any packaging which supports any one or two objects could have equally sufficed.

As a result of these five differences, claim 1 is properly believed to be in condition for allowance.

As to claim 3, neither of the references show a raised portion for "fitting in" a main opening because (a) Sagstetter doesn't have a common space shared opening, and neither Sagstetter nor Seeley have any sort of projection into such a main opening.

As to claim 5, Sagstetter has a needle engaging member which includes projections, but Sagstetter lacks the other limitations of claims 4, 2, & 1.

As to claim 8, the claim language "further comprising at least one container in communication with said main opening for the disposal of miscellaneous dangerous material" As Sagstetter has no main opening, it similarly has no container in communication with it for disposal of miscellaneous dangerous material. The claims set requires all of the structures, including engagement AND retaining members; a main opening in communication AND a container for disposal of miscellaneous dangerous material. The structure of Sagstetter is so different

that it can't be made to be viewed as containing the limitations of claim 8.

As to claim 9 the shape of the container is inventive and not simply a design choice.

As to claim 11, the use of adhesive with a structure which includes including engagement AND retaining members is new and not old and conventional.

As to claim 13, it provides a limitation which facilitates its function to engage AND retain the needles. It is not therefore simply a matter of design choice.

As to claims 16-18, and specifically with respect to claim 16, the use of Sagstetter promotes cross contamination. The moment that a needle is inserted into members of openings 35, 50, all of the cross contaminated needles in the main compartment continue to cross contaminate each other and to cross contaminate the needle inserted. In the structure of the invention, once the step "c" is accomplished, "de- coupling said hypodermic needle from said hypodermic syringe, to isolate said hypodermic needle and inhibit its cross contamination" the structure taught enables this step to ISOLATE the needle from everything else. Attempting these steps under the teaching of Sagstetter results in extreme contamination.

Other limitations of the remaining steps only serve to further distinguish and limit the invention.

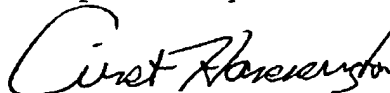
The allowable subject matter of paragraph 5 is noted, however it is believed that ALL of the claims are allowable and therefore conversion of the "objected to" claims to independent form will not be necessary at this time.

As a result, it is believed that claims 1-19 are currently in condition for allowance and such is earnestly solicited.

The Examiner is invited to telephone Applicant's Attorney at the number below between the hours of 1:00 p.m. and 6:00 p.m. Eastern Standard Time, if such will advance this case.

Dated: October 27, 2003

Respectfully submitted:

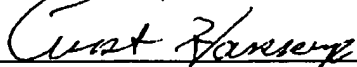


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DATE OF DEPOSIT: October 27, 2003

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